California Health Policy and Data Advisory Commission
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Minutes of Meeting

AB 524 TECHNICAL ADVISORY COMMITTEE

September 5, 2003

Committee Chairman, Jerry Royer, MD, called the meeting to order at approximately 10:00 a.m., at the Sutter Square Galleria, 2901 K Street, Room 206, Sacramento, California.

Present:

Douglas Bagley
Robert Brook, MD
Marilyn Chow, RN, DnSC
Laura B. Gardner, MD, MPH, PhD
Maida Reavis Herbst, RHIA
Earl Lui, JD (Consumers Union)
Diana Petitti, MD
Jerry Royer, MD, MBA
Jeffrey Rideout, MD
William S. Weil, MD

Absent:

Nancy Donaldson, RN, DnSC
David Hayes-Bautista, PhD
Mark Hlatky, MD

Laurie Sobel, JD (represented at meeting)

Contractors:

R. Adams Dudley, MD, MBA
Andrew Bindman, MD

Staff Present: **CHPDAC**: Jacquelyn Paige, Executive Director; Anne Mox, Executive Assistant
OSHPD: David M. Carlisle, MD, PhD, Director; Dale Flournoy, Interim Chief Deputy Director; Joseph Parker, PhD, Acting Deputy Director, Health Care Quality and Analysis Division;Steve Lubeck, PhD, and Zhongmin Lee, PhD, Health Care Quality and Analysis Division

Chairman's Report: Dr. Royer announced that he will be returning to California to accept a position as Senior Medical Director for HealthNet in Northern California, effective October 20.

OSHPD Director's Report: Dale Flournoy, Acting Interim Chief Deputy Director, introduced himself. He has been with OSHPD's Cal Mortgage Loan Insurance Program for approximately 20 years, a billion dollar operation in California

focusing on tax-exempt revenue bonds for health care. Prior to that, he was with the Department of Finance and the Department of Transportation, basically dealing with budgets and public policy.

When Bud Lee submitted his resignation, Dr. Carlisle decided to use current Deputy Directors or other executive staff members to fill the Chief Deputy Director position on a rotating interim basis. Dale Flournoy was asked to take the first rotation.

OSHPD is a $50 million operation, operating with about 350 personnel in five divisions with seven different funding sources. Over the last fiscal year, there was a reduction of about ten percent in person years (Pys). Another reduction was made in the current year, with no actual or pending layoffs. The Department of Finance had been treating specially-funded agencies the same as General Fund agencies. OSHPD is principally funded from non-General Fund sources.

Departments are working on the next fiscal year budget (2004-05) and are being warned of another set of potential cuts. Also, budget change proposals (BCPs) are being prepared for the next fiscal year. OSHPD is requesting programmatic increases in staff, without increases to the general fund.

In addition to the ten percent reduction taken by OSHPD as part of the formal budget process, the Department of Finance has decreed that vacant positions through normal turnover are automatically lost.

One vacant position eliminated is that of Deputy Director for the Healthcare Quality and Analysis Division, vacated in February or March. It is anticipated that the position will be returned. The implication for the division is that there will be slower production of outcome reports, with a continuing commitment to increase the scope and breath of outcomes reports, such as pneumonia and maternal outcomes. The CABG report release is imminent.

Approval of Minutes:

The contents of the minutes from the September 24, 2002 meeting were approved, with some editing and proofreading.

Update on Healthcare Quality and Analysis Division: Joseph Parker, PhD, Acting Deputy Director

Voluntary CABG Report (CCMRP): Copies of an embargoed CABG technical report for years 1997 through 1999 were distributed to Committee members. The report is embargoed until its release on Monday, September 8. The report has been distributed to the 70 hospitals, that voluntarily participated in the project. The voluntary CABG activity will continue as an ongoing project even though the mandatory CABG program has begun.

Two sets of data are provided in the report. Not all hospitals participated and reported CABG data from 1997 through 1999, although all hospitals reported 1999 data. Some

hospitals withdrew after seeing their results. An advisory panel chaired by Dr. Brook, including Andy Bindman, has been advising on the project, and gave permission to report two sets of data for this report.

In the last report, about two years ago, the relationship between risk-adjusted mortality and hospital outcomes was explored. There was no significant relationship between the two. Much literature suggests that practice makes perfect and the more CABG procedures done, the better the outcome. This report finds that hospitals having fewer than 200 cases annualized are statistically significantly worse than those with annual volumes of over 300.

The hospitals in this analysis were broken into different volume groups. Approximately 80 percent of California hospitals would be defined as low volume, using the standards that New York and Pennsylvania use.

In 1999, no hospital did really well. When the results are rolled up, there is a much more balanced number of worse-than and better-than results, due to the fact that with low volume hospitals, the confidence intervals around their expected mortality are very wide. When the data are aggregated across years, the confidence intervals become narrower. None of the 70 hospitals performed significantly better than expected in 1999. However, for the all-years analysis, there were five better-than expected hospitals and six worse-than expected results. This is expected in an outcomes study of this nature.

An analysis was done this year concerning participants versus non-participants. The raw mortality rates are statistically different. A very small analysis compares the risk-adjusted outcomes for hospitals that participated and the hospitals that withdrew.

The voluntary report release date has been delayed, because the mandatory program was initiated, and all resources were devoted to that activity.

Staff is working on data from 2000 and 2001. The voluntary program ends with 2002 data. The mandatory program (C-CORP) begins with 2003 data. About 75 hospitals are submitting data for 2000-01. Only about 50 hospitals are submitting data for 2002. It is thought the drop off is due to the start up of the mandatory program, which is the first priority. The quality of the data is improving. A lot of modeling can be done with the voluntary data, as well as approaches to cleaning the data and good validation strategies. Staff is interested in looking at 30-day mortality, operative mortality as opposed to inpatient mortality, which the models are. Working with CCMRP data allows the linking of patient discharge data with vital statistics. Staff is exploring integrating clinical data with the administrative data because it is superior to administrative data. California has probably the best quality administrative data in the United States.

There are not sufficient resources to support the mandatory program. Of the four positions allocated for this program, one position has been filled. Joseph Parker, PhD, is filling in as Acting Deputy Director position on an interim basis. Dr. Parker's former position as Director of Clinical Data Programs has not been replaced, and he has been acting in both capacities.

Audits suggest that the clinical registry standards and data collection tools used by hospitals, most of which comes from the National Society of Thoracic Surgeons, has several problems. Audit results revealed that many deaths were misreported. When cross-validated with patient discharge data indication of in-hospital mortality, it was found that patient discharge data were correct. A major concern is when PTCA crashes for angioplasties go wrong that result in immediate CABG procedures, some hospitals seem to be coding those, yet there is no such record in the patient discharge data. When going back to hospital records, there was no PTCA during that admission prior to CABG. Rollover patient discharge data are being found, so there might be a reason to link it with the clinical data to improve the models. This is not done in California and not done much in other states.

For CCMRP, there may be a release of 2000-01 data, which are being aggregated in 2004. This depending on staffing and services, but cannot be done within the current resources.

Staff is considering reducing the size of future reports, which contain lengthy discussions of methodology. As these reports become more common and generally accepted by the public and the health industry, the reports can be made more consumer friendly.

Dr. Brook said the State has been compulsive in trying to assure the quality of the data before releasing a report as opposed to just writing what ought to be done. The State should not have to pay for auditing the data from hospitals in order to produce accurate reports in a timely manner. The hospital industry should assume some responsibility for submitting good data initially. A data report should not contain data that are three years old by the time the report is released. It could possibly be a one-year exercise if there were resources and had the full cooperation of hospitals.

Mandatory CABG Reporting (C-CORP): With C-CORP, reporting should be less of an issue because OSHPD dictates deadlines to hospitals that they have to abide by or be penalized. The report will be a one-year report at the hospital level, released in 2005. The second report will be based on 2003-04 data, and include surgeon level analysis and results to be released in July 2006.

It was suggested that a report could be released, with a follow-up audit such as done with the reporting of financial data. Dr. Brook said if the market is going to work as opposed to a regulatory approach, it can only work if we are serious about implementing it. The advisory committee basically said the hospital should be reported, willing to be audited, and submit good data. We are missing an opportunity on how to play that out politically.

The volume outcome issue of California hospitals in surgery is awful. If Leapfrog criteria were implemented for the four or five operations with which they deal, there may not be a single hospital in California that meets Leapfrog volume criteria in all four procedures. If there is no outcome or process data, Leapfrog will push vendors or providers to focus on volume.

Dr. Brook thought there is a responsibility by hospitals to submit accurate data, and models in the production mode should be available for release as soon as the data are received. Committee member Bagley asked about the resource effort once the data are received to run the models and issue a report. Dr. Parker said it is not as much a resource drain. Staff is working on a hospital outcomes analysis module for an on-line report to go to the hospitals immediately informing them about their risk-adjusted results on a confidential basis. This would be in synchronization with the data reporting cycle from MIRCal. Thirty-day mortality is involved, and OSHPD would also synchronize with Vital Statistics records. Legally, OSHPD is required to give a 60-day hospital review.

A table could be produced almost instantaneously if the data were perfect. To distribute it could require approval from the Health and Human Services Agency and Governor's Office. Committee member Bagley said he is talking about running the data through the model and getting the results immediately for models that have already been approved and are not new models. The accumulation of the data and complying with processes after the run of the model is complete consumes lots of time.

Model developing should be done after the data are released. It should be a routine process if you have the model to just feed the data into the model. Routine process could be done very quickly. It is more important to release the data quickly than to refine it down to one more hundredth of a decimal point. Dr. Royer requested that the minutes clearly reflect the Committee's concern about timely reporting.

Dr. Parker continued with his presentation. There are 120 hospitals and 321 surgeons performing CABG surgeries. Many of the surgeons are performing surgeries at more than one hospital. One hospital closed mid-year. There are 25,000 isolated CABG surgeries performed annually; 4,500 non-isolated surgeries performed. All the data for CABG surgeries are collected in order to make a final determination of whether it is isolated or not. There has been a volume decline in CABG surgeries, 13 percent from 1997 through 2002. There has been an increase in PTCA of approximately 25 percent, which are not reported. The isolated CABG mortality rate has also declined. A legislative bill has been introduced which would require OSHPD to report on PTCA outcomes. It was introduced in the first year of a two-year legislative cycle.

Bagley asked what were the explanations for the mortality decline. Dr. Parker explained that CABG is well studied and best practices are in place throughout the United States. Dr. Brook said ninety percent of the deaths from CABGs occur on five percent of the population. For most, CABG is a very safe operation. There is about a three percent death rate, or about 900 deaths. The death rate for pneumonia, stroke, and heart attacks is much higher.

A clinical advisory panel recommended the data elements to be collected (most of which were nationalized STS data elements), and reviews and approves the risk-adjustment model, and adjudicates physician appeals. Appeals are for severely ill cases where the physician does not agree with the death attributed. To speed up the process, surgeons agreed to certify their data upon submission. They will be provided multiple data correction opportunities. There is a mandatory 30-day review of the final

ratings by physicians and hospitals, which is the appeals process. The panel has been provided with authority to exclude individual surgeons for statistical or technical considerations, which means they will not appear in the report.

There are 52 clinical data elements, 36 risk factors, 5 process measures, and 11 elements are for identification. There are three basic methods for collecting the data. About 70 percent out of 120 hospitals use STS vendor software. These surgeons are members of the National Society of Thoracic Surgeons and report their data, which contains 217 data elements. This is modified to report the 52 clinical data elements for California. OSHPD has developed a tool for hospitals to report data, and about 45 hospitals use this method. These hospitals are usually smaller volume hospitals that could not afford to use STS software. There are ten certified STS vendors in the State of California, charging between $10,000 and $20,000 for a system per hospital to report their data. They see OSHPD as competition, as it cost about that to actually create OSHPD's system.

There are 21 hospitals that have submitted test data to OSHPD. Only seven hospitals have passed. There have been three official submissions, all of which passed. Two of these used OSHPD's tool.

The first report for mandatory CABG reporting is due in 2005. The first physician public report is due July 2006. Hospital data submission for the first six months of 2003 is due the end of September. Only 30 extension days will be allowed before a hospital is fined for late data submission.

CABG data are being submitted mostly from nurses in the cardiothoracic units. Program requirements can be complex and burdensome for hospital personnel not accustomed to reading regulations. Some of the STS software vendors are behind in giving the hospital the California module to report data. OSHPD has several web pages containing questions and answers about the regulations. The clinical advisory panel made some changes to data definitions, which caused some confusion.

It is expected that there will be delays in the surgeon level reporting. Dr. Petitti said she would like to see more optimism about meeting the deadline rather than setting up permission to have a delay. The clinical advisory panel will probably be interested in the methods used for reporting and volume thresholds. OSHPD has had the general goodwill of the hospitals.

Community Acquired Pneumonia: The preliminary first pneumonia report has been completed and feedback has been received. This report was based on a 1996 development and validation study done by Dr. Jennifer Haas. The report has been approved by the Director's Office and staff is preparing for the mandatory 60-day review by hospitals. Since this is a new report, it will need approval by the Health and Human Services Agency and Governor's Office before release to the public. Mr. Bagley suggested that OSHPD look for ways to shorten the time frames. It was suggested that OSHPD should encourage other organizations to be supportive of things like outcome studies. The main problem is data verification and correction and staffing. With the budget crisis, there has been no special exemption for special-funded departments to fill

positions, although now that the budget has been signed, the Department of Finance is now revisiting this issue.

The report represents 406 hospitals, with approximately 200,000 patients. The report incorporates "do not resuscitate (DNR)" within 24 hours after admission as a risk factor. Only hospitals that perform as outliers on both a model with DNR and a model without DNR are deemed ultimately to be worse than or better than expected. This was supported by the TAC, and was implemented. This is the first time "condition present at admission (CPAA)" has been used to distinguish between acute conditions prior to admission and those that followed, which are generally complications. Dr. Haas has done a validation and thought it was sufficient. All states except California have had a problem of inability to use ICD-9 codes to distinguish between acute conditions, pre-op or prior to admission, and those occurring afterwards.

Dr. Brook said the TAC discussed very clearly the notion that the two models used hospitals as outliers in either one of the models, and they should be labeled as worse than expected. After looking at the report, it should be the technically correct solution. On the better side, they would have to be better on both of them to be better. That would identify more hospitals in the worse than expected area. The models have the ability to flip a hospital at the .05 level. Dr. Brook urged the TAC to rethink the policy that when there are multiple models, both of which have some validity, that on the worst side use criteria that if you fail on one, you fail. On the better side, it has to be on both models. This notion will be carried forward as an **agenda item** at the next meeting.

<u>California Intensive Care Outcomes (CALICO) Project</u> – R. Adams Dudley, MD, MBA, Principal Investigator

There have been four widely used ICU models. Three models have been used for a long time in the public domain, the Mortality Prediction Model-II, SAPS-II, and APACHE-II. Until recently, APACHE III was proprietary. CALICO is first to procure it, use it, and give it complimentary to users. Predictive accuracy comparisons of these models using modern data are not available.

MPM-II is composed of 15 variables; SAPS-II is 52 variables, and APACHE-II is 75 variables, plus a detailed reason for admission. APACHE-III uses some additional clinical variables beyond APACHE-II, and some utilization variables.

In actual use in the clinical and academic worlds, APACHE-III is the most used. Most data studies from the late 1980s and early 1990s showed C statistics that were better with APACHE-III than with other models. However, it is clear even when they have the same statistic they do not always identify the same hospital as doing well or poorly. This calls the overall validity into question. There is a problem of "no gold standard."

CALICO compares the ICU models using very recent data. The project is voluntary and cannot be called a representative sample of California hospitals. There is a selection factor of the volunteering hospitals, and may not be based on quality of ICUs. Each hospital is asked for the number of ICU admissions per year. Based on the number of ICU admissions per year, hospitals were asked to give a sample that varies in size.

Only adult ICU admissions are used. Patients are over 18 years of age, admitted to the ICU, and stay at least four hours. There are no burn, trauma or CABG patients.

In 2002, only 23 hospitals were included, with 5,000 patients admitted to ICUs. It is expected there will be about 40 hospitals in 2003, with about 15,000 patients. Hospitals are required to license beds as ICUs but are not required to use them. It is hard to determine the number of hospitals that have functioning ICUs.

The data sample of 2002 seems to be quite good for most of the data elements. It is not difficult to collect clinical items like the lowest blood pressure accurately. The reason for admission is the most difficult to collect. Each hospital collects data from 40 charts and then stops. A secure Internet link has been set up to capture the hospital data. The contractors randomly select patients and audit 10 of the 40 charts. The data about data quality comes from the audits. The audit findings show that 77 percent of the time there is full agreement on the reason for admission. About 10 to 15 percent of the time, it is not the exact same diagnosis, but it would not change the weight in the models. It would change the weights of the models in only 10 percent of the time.

The correlation coefficient between what the auditors would have scored the patient and what the hospitals scored the patient is over .9, which is excellent overall data quality. The reason for admission and the chronic health conditions actually give a fair number of points in some of the models, and are fairly rare. A little bit of disagreement leads to a low kappa. The Cleveland Health Quality Choice thought it better to discard many of the rare things; investigators will continue to pay attention to the possibility that this might be the best answer or patient discharge data confirmation.

The excellent data may actually reflect the fact that the audits were done early. There is an all-day training session that includes a description, plus some cases, and some cases they do for homework. They then work on the 40 cases, submit them, and are audited, all within a fairly close timeframe. In a hospital, the time lapse might decay the quality toward the end. Also, by auditing at the beginning, there might be more of a data quality problem.

Software has been changed for 2003, looking at patterns of mistakes made, and inserting additional reminders. Also, more crosslinks have been added. By having the experience of last year, training will be improved. Newsletters will also be used.

Data collection for 2002 began before APPACHE-III model was given. In an effort to only collect necessary items, some extra data were not collected that go with the APACHE-III model. JCHO has been headed in the direction of APACHE-III, so all of APACHE-III is being added.

The HL (Hosmer Lemeshow) statistics are significant for each of the models, which means a calibration problem. The graph shows what is needed to fix the problem. All the models have poor calibration. ICU care is probably better now than it was in the 1980s. All predict higher mortality than has been observed in the CALICO population.

The modeling has not been redone. All that is being said is the regression coefficients developed at another external population do not hold. Dr. Brook suggested comparing data with Kathy Rowan of the United Kingdom, who will be visiting soon. The models need to be re-estimated to add a fudge factor. The main focus is determining the additional clinical data elements that are needed, by comparing the models and determining if there are models that could achieve the same thing for less data.

For hospitals, there are some differences in the individual numbers. The biggest difference is in smaller sample size hospitals.

The agreement with the participating hospitals is that reporting of outliers would be confidential for the first year. Participation is voluntary and hospitals can drop out at any time.

Dr. Dudley asked the TAC if it wanted to focus on outliers which will be relatively few, or as employers would like, to have more categories to see more differentiation. Under either of the models, there is not much difference.

JCAHO has followed the TAC 's lead and wants to add a fifth core measure, ICU, which is reflecting pressure from the employers to do something about ICU care, which actually consumes one percent of the GTP. Leapfrog has developed some ICU standards and has tried to get National Quality Forum to endorse something. It is the employer's intention to tack that into the voluntary CMS public reporting as soon as possible, and wants to initially recommend using APACHE-III.

When JCHO did the alpha test, the hospitals said they did not believe APACHE-III is really better to justify the extra data collection and cost. JCAHO has now decided to partner with CALICO to figure out the issue. It wants a model and needs to know the comparisons and how much data are required. It is actually going to use CALICO software and training materials. CMS has the voluntary public reporting and Leapfrog wants public reporting.

With the 2003 model building, more information will be obtained about the costs of collecting the data, which will be an explicit component of the collaboration with JCAHO. Nationally, a sample of 100 hospitals will be used. Every hospital will begin collection for four months. It is not part of CALICO, but they will use CALICO for three months. In the last month, they will use APACHE-III for one week, SAPS for one week, and MPM for one week. There should be good information on the costs for the collection.

According to the contract, the investigators will create an preliminary version of a public report, which will not disclose the name of hospitals. The TAC can advise if the report should be released.

AHRQ has offered CALICO hospitals additional benefits to collect process of care information in their ICUs. The hospitals will receive their overall performance, and CALICO will report back to them on how their processes are doing. The gold standard would be the model works for hospitals with good mortality performance to look at their underlying processes for care and also see good process for care.

No physician identifiers will be collected. Hospitals know who their patients are and can link with the physicians. CALICO will give hospitals the overall mortality rate.

All four models will be compared and at least two new models will be developed, one will use a subset of the clinical data, and one will use ICD-9 codes and demographics only. Recruitment of more hospitals to participate is needed.

Dr. Brook suggested pushing for implementation of the 15 data elements for ICU patients. There is a detailed compelling and voluntary sample with huge variations, consistent across the three different methods of collection. There is a law that says OSHPD can collect up to 15 additional data elements, including clinical data. This should be combined into something that will stimulate some action.

The contract states that a public report will be issued for the second year data. Forty hospitals out of 400 are participating. Question was asked whether the report should be issued, based on CALICO, which consists of 90 or more elements, and APACHE-III, with 78 elements. CALICO will remain in the public domain. It was thought that process as a care issue is a good move.

Issues to be considered:

1. Adoption of the 15 data elements.

2. Release of the report. There is enough justification to write a report that supports the use of the 15 variables, ICU is one percent of the GDP, it affects most of the California hospitals, and there is a large variation in voluntary hospitals.

3. Determine the best model. The models when standardized using the simplest of statistical techniques are very consistent.

The question was asked of what would happen after the 40-hospital study is done. Recruitment of more hospitals will be done. The office will look at whether or not transfers are a major issue and if there is a different mortality performance. APACHE-III would be added. Dr. Brook said he had a conflict of interest.

Identify clinical data elements, which probably in combination with patient discharge data elements could be used to get a good model to report on ICU outcomes. Even if they start with regulations now, it would be a minimum of 18 months before hospitals could begin reporting. Continue with the validation process. Show that the model picked validates to processes and has a reasonable C statistic, and that the data can be collected relatively accurately.

There are different ways to achieve the collection of ICU data. One is to obtain legislative authority, similar to the CABG program, and require hospitals to report certain data elements. Another way is to determine that the 15 data elements are essential and add them. The clinical data elements might be useful for other conditions. The TAC fought for those 15 data elements, and must be clear on how to use them.

Dr. Dudley said he thought this should be its own program, like CCMRP. It should be set up so hospitals submit data over the Internet right away. If the simpler model is used, it is quite possible that the same level of verification would not be needed. Instead of waiting for the entire corrections and edits of the patient discharge data, set it up as a separate program. Take software and lop off most of the variables, do the Internet reporting, which is safe and secure, and this could be done faster.

This might argue to have some influence and publish reports to halt JCAHO's drive towards APACHE-III.

Dr. Dudley suggested moving in parallel to obtain legislation for a program and build in flexibility. The number of variables goes up and down. Have a backup. If APACHE-III becomes the core measure for JCAHO, then the 15 elements are not used up.

The MIRCal system would have to be changed to accept the 15 data elements, which would involve regulations.

Dr. Carlisle suggested and, by consensus, the TAC agreed, that it might be better and safer to proceed in both directions to get a better sense of which way to actually go.

Dr. Brook suggested that Dr. Dudley follow up on how to guard the system from gaming by deleting those patients that are not capable of being cured and not offering them ICU care. Look at the proportionate deaths for the common conditions that produce the deaths in the ICU, and whether they occur among those that went through the ICU or not. Look at hospitals with very low death rates in the ICU – a lot of the deaths occur for those same conditions that did not go into the sample.

Dr. Dudley said once this is in place, a question should be asked if the person went to the ICU, and should this count as one of the 15 elements.

Adjournment: The meeting adjourned at 1:40 p.m.